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## TELECOPY COVER SHEET

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**Date:** **July 15, 2003**

**TO:** **Name:** **Examiner Sakelaris**

**Company:** **U.S. Patent and Trademark Office**

**Address:** **Group Art Unit 1634**

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**FROM:** **Sender:** **Jennifer E. Grant**

**Number of Pages INCLUDING This Cover Sheet:** **10**

**Docket No.:** **EXT-036**

**U.S.S.N.:** **09/514,865**

**Comments:**

**2653080**

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**PATENT**  
Attorney Docket No. EXT-036

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Shuber  
SERIAL NO.: 09/514,865 GROUP NO.: 1634  
FILING DATE: February 28, 2000 EXAMINER: Sakelaris, S.  
TITLE: METHODS FOR DISEASE DETECTION

**CERTIFICATE OF FACSIMILE TRANSMISSION**

I hereby certify that this correspondence, and any document(s) referred to as attached hereto, is/are being transmitted to the United States Patent and Trademark Office, Facsimile No. (703) 308-8724 on this 15th day of July, 2003.



Thomas F. Hellenthal

Attached hereto is/are:

Transmittal Form (1 pg.); Fee Transmittal (1 pg.); Copy of Fee Transmittal (1 pg.); Letter to Examiner (1 pg.); Terminal Disclaimer (3 pgs.); and Notification of Loss of Entitlement of Small Entity Status (37 CFR §§ 1.27 and 1.28) (1 pg.).

# TRANSMITTAL FORM

Application Serial Number	09/514,865
Filing Date	February 28, 2000
First Named Inventor	Shuber
Group Art Unit	1634
Examiner Name	Sakelaris, S.
Attorney Docket No.	EXT-036
Patent No.	Not applicable
Issue Date	Not applicable

**ENCLOSURES (check all that apply)**

<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Check Attached <input checked="" type="checkbox"/> Copy of Fee Transmittal Form	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application <input type="checkbox"/> Formal Drawing(s)	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences <input type="checkbox"/> Appeal Brief (in triplicate)
<input type="checkbox"/> Amendment/Response <input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets _____]	<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal <input type="checkbox"/> Power of Attorney (Revocation of Prior Powers) <input checked="" type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Status Inquiry <input type="checkbox"/> Return Receipt Postcard <input type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8 <input checked="" type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
<input type="checkbox"/> Petition for Extension of Time	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	<input checked="" type="checkbox"/> Additional Enclosure(s) (please identify below) <input checked="" type="checkbox"/> Letter to Examiner
<input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Form PTO-1449 <input type="checkbox"/> Copies of IDS Citations	<input type="checkbox"/> Small Entity Statement <input type="checkbox"/> CD(s) for large table or computer program <input type="checkbox"/> Amendment After Allowance <input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)	<input type="checkbox"/> Notification of Loss of Entitlement of Small Entity Status (37 CFR §§ 1.27 and 1.28)
<input type="checkbox"/> Certified Copy of Priority Document(s)		
<input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above		

**CORRESPONDENCE ADDRESS**

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**SIGNATURE BLOCK**

Respectfully submitted,

  
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 High Street Tower  
 125 High Street  
 Boston, MA 02110

**FEE TRANSMITTAL  
FY 2003**

<i>Complete if Known</i>	
Application Serial Number	09/514,865
Filing Date	February 28, 2000
First Named Inventor	Shuber
Group Art Unit	1634
Examiner Name	Sakelaris, S.
Attorney Docket No.	EXT-036

**PATENT**  
Attorney Docket No. EXT-036

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Shuber

SERIAL NO.: 09/514,865 GROUP NO.: 1634

FILING DATE: February 28, 2000 EXAMINER: S. Sakelaris

TITLE: Methods for Disease Detection

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**LETTER TO EXAMINER**

As discussed and agreed upon with Examiner Sakelaris during a telephone conversation with Daniel A. Wilson and the undersigned attorney on July 14, 2003, it is the Applicant's understanding that the Examiner will insert the phrase "using an assay that detects said nucleic acid regardless of whether said nucleic acid is mutant or wild-type," between the words "length" and "present" in pending claim 1. This amendment is without any intention of disclaiming equivalents thereof. It is also the Applicant's understanding that the Examiner will add new dependent claim 5, reciting "The method of claim 1, wherein said nucleic acid comprises human nucleic acid." As further discussed with Examiner Sakelaris on July 14, 2003, Applicant also submits herewith a Terminal Disclaimer.

Upon entry of Examiner's amendments, claims 1 and 3-5 are pending and in condition for allowance. The Director of the U.S. Patent and Trademark Office is authorized to charge Deposit Account No. 20-0531 for the fee under 37 C.F.R. 1.20(d) and any other fee required for entry and consideration of this paper.

Respectfully submitted,

Date: July 15, 2003  
Reg. No. 51,752

Tel. No.: (617) 310-8423  
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*Jennifer E. Grant*  
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**PATENT**  
Attorney Docket No. EXT-036

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Shuber

SERIAL NUMBER: 09/514,865 GROUP NUMBER: 1634

FILING DATE: February 28, 2000 EXAMINER: S. Sakelaris

TITLE: Methods for Disease Detection

**Terminal Disclaimer**

I, Thomas C. Meyers, residing at 3 Great Rock Circle, Natick, MA 01760, state that I am authorized to sign this Terminal Disclaimer on behalf of Exact Sciences Corporation (hereinafter EXACT), identified below as the assignee of the entire right, title and interest in and to the above-identified patent application, U.S. Serial No. 09/514,865. I have reviewed all the evidentiary documents accompanying or referred to in this Terminal Disclaimer and certify that, to the best of my knowledge and belief, title to the above-identified application is in the name of EXACT.

EXACT, having a place of business at 100 Campus Drive, Marlborough, MA 01752, is the assignee of the entire right, title and interest in and to the above-identified application, 09/514,865, by virtue of the Assignment recorded in the United States Patent and Trademark Office at Reel 010964, Frame 0872, on July 14, 2000, by the inventor in this application to Exact Laboratories, Inc., and the Change of Name document indicating a name change to Exact Sciences Corporation, recorded in the United States Patent and Trademark Office at Reel 011676, Frame 0640, on April 2, 2001. EXACT is also the assignee of the entire right, title and interest in and to co-pending application U.S. Serial No. 09/545,162 by virtue of the Assignment recorded in the United States Patent and Trademark Office at Reel 010991, Frame 0831, on July 21, 2000, by the inventors in that application to Exact Laboratories, Inc., and the Change of Name document indicating a name change to Exact Sciences Corporation, recorded in the United States Patent and Trademark Office at Reel 011661, Frame 0276, on April 2, 2001.

Terminal Disclaimer  
U.S. Serial No. 09/514,865  
Page 2 of 3

EXACT hereby disclaims any portion of the term of a patent issued on application Serial No. 09/514,865 that would extend beyond the expiration date of the full statutory term of any patent issued on application Serial No. 09/545,162. EXACT hereby agrees that any patent so issued on application Serial No. 09/514,865 shall be enforceable only for and during such period that the legal title to said patent issuing on application Serial No. 09/514,865 shall be the same as the legal title to any patent issued on application Serial No. 09/545,162, and that this agreement shall run with any patent issued on either of the above-referenced application Serial Nos. 09/514,865 or 09/545,162 and be binding upon the Assignee, its successors or assigns.

EXACT does not disclaim any portion of the term of any patent issued on application Serial No. 09/514,865 due to a failure to pay a maintenance fee, a holding of unenforceability or invalidity, a statutory disclaimer, the cancellation of claims by a re-examination certificate, or if said patent is otherwise terminated prior to expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

EXACT further disclaims the terminal portion of any patent issued on application Serial No. 09/514,865 which would extend beyond the full statutory term of U.S. Patent No. 6,586,177, filed December 7, 1999, or U.S. Patent No. 6,143,529, filed March 24, 1999, and hereby agrees that any patent so issued on U.S. Serial No. 09/514,865 shall be enforceable only for and during such period that the legal title to said patent shall be the same as the legal title to U.S. Patent Nos. 6,586,177 and 6,143,529, and that this agreement shall run with any patent issued on application Serial No. 09/514,865 and be binding upon the Assignee, its successors or assigns.

EXACT does not disclaim any portion of the term of any patent issued on application Serial No. 09/514,865 prior to the expiration date of the full statutory term of U.S. Patent Nos. 6,586,177 or 6,143,529 in the event that either of said patents expire due to a failure to pay a maintenance fee, a holding of unenforceability or invalidity, a statutory disclaimer, the cancellation of claims by a re-examination certificate, or if either of said patents is otherwise terminated prior to expiration of its statutory term as presently shortened by any terminal disclaimer, except for the separation of legal title stated above.

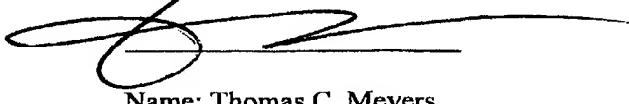
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made in the knowledge that willful false statements and the like so made are punishable by fine or

Terminal Disclaimer  
U.S. Serial No. 09/514,865  
Page 3 of 3

imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful  
false statements may jeopardize the validity of the application or any patent issued thereon.

Exact Sciences Corporation

By their attorney,



Name: Thomas C. Meyers  
Reg. No. 36,989  
Date: 7/14/03

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